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Title

Dietary Risk Assessment of Sabretech QS

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA '10(d)(1)(A), (B) or (C).

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GOOD LABORATORY PRACTICES STATEMENT

This study does not meet the requirements of 40 CFR Part 160. No quality assurance unit was in place. No study director was assigned.

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Dietary Risk Assessment of Sabretech QS

Clearstream Technologies LLC manufactures the end use product Sabretech QS, an antimicrobial product intended to preserve finished food contact articles such as food preparation surfaces, polymeric tubing for beverages, and activated carbon water filters. Sabretech QS comprises the active ingredient 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride at 1.0%. The maximum use level of the active ingredient in finished food contact articles is 1% by weight of the resin, laminate, coating or polymeric tubing. In activated carbon water filters, the maximum use level is 0.25% by weight of the carbon block.

Products that use Sabretech QS in the coating, film or laminate are: appliances and equipment, barrier fabrics, building materials and components, collection and storage equipment (such as conveyor belts, piping systems, silos, tanks and process vessels), cookware, countertops, food wrap (including coated deli paper, coated meat interleavers and plastic wrap), general purpose containers, glazing for cement tile, glazing for vitreous china used in plumbing fixtures (such as sinks and countertops), industrial equipment, natural and synthetic fibers and fabrics, packaging, paper products (such as wipes, tissues, wall coverings, towels), plastic film, and sinks. Products that use Sabretech QS in polymeric tubing include beverage dispensing equipment tubing and beverage processing equipment tubing.

Hazard Characterization

The acute toxicity study database for Sabretech QS indicates low acute toxicity by the oral, dermal and inhalation routes (Category IV) (EPA 2017). Sabretech QS is mildly irritating to the eyes (category III) and skin (Category IV) and is not a dermal sensitizer

U.S. EPA (2007) did not identify toxicological endpoints of concern for repeated oral or dermal exposure to trimethyoxysilyl quaternary ammonium compounds. This conclusion is based on the low toxicity in acute, subchronic and developmental studies conducted with trimethoxysilyl quaternary ammonium compounds. There were no effects up to and including the highest dose tested in the 90-day oral, 90-day dermal, and developmental toxicity studies. There is no concern for genotoxicity based on the results of the mutagenicity and clastogenicity studies.

The US FDA Threshold of Regulation (TOR) exemption of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride further indicates that this compound has not been shown to be a carcinogen, nor is it similar structurally to any known carcinogen. Furthermore, it does not contain a carcinogenic impurity with a TD50 value of less than 6.25 mg/kg bw/day (21 CFR §170.39; TOR No. 2013-001).

Dietary Exposure

U.S. FDA exempts substances from regulation as food additives when they are present in food at a level that results in a dietary exposure of 0.5 ppb or less in the diet: the Threshold of Regulation (TOR) (21 CFR §170.39). Dietary exposure to 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is equal to or below FDA's TOR when used as a preservative in finished food preparation surfaces,

polymeric tubing for beverages, and activated carbon water filters at use levels equivalent to those that Clearstream's Sabretech QC label indicates (TOR No. 2013-001; see above). There are no limitations on the food type or use temperature. The estimate of dietary exposure was based on the assumption of 100% migration into food/beverages over the life of the treated article; maximum of 1% incorporated into the treated materials; 0.9 – 1.2 g/cm^3 density of polymeric laminates, thin films and coatings; materials' thickness ranging from 0.0005 to 0.005 inches; even distribution of active ingredient throughout the treated materials where food contacts the surface of the treated article and only penetrates 1-3 mils.

EPA (2016) modified the level at which there is no reasonable expectation of residues from FDA's TOR value of 0.5 ppb to 10 ppb, a reference to the historic detection limits for most pesticides

Dietary Risk Characterization

The available information presented in this assessment supports the position that there is reasonable certainty that no harm to humans will result from the use of Sabretech QC as a material preservative added to finished food contact articles at a maximum of 1% by weight of resin, laminate, coating or polymeric tubing, or 0.25% by weight in activated carbon water filters. There are no toxicological endpoints of concern for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride and dietary exposure to 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride as a result of these uses will not exceed 10 ppb (mg a.i./kg diet).

References

21 CFR 170.39. Threshold of regulation for substances used in food-contact articles.

US EPA. 2007. Reregistration eligibility decision for trimethoxysilyl quaternary ammonium compounds. EPA 739-R-07-007.

U.S. EPA. 2016. Human health and ecological risk assessment for proposed new food contact uses of HM4100. Memorandum dated 9/21/16.

US EPA. 2017. Acute Toxicity Review for SabreTech QS, EPA Reg. No.: 92057-G. DP 442969. Memorandum dated 12/6/2017.